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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/789,134

02/27/2004

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10,398

6767

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04/08/2008

EXAMINER

HOFFMAN, MARY C

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

04/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,134	JACKSON, ROGER P.	
	Examiner	Art Unit	
	MARY HOFFMAN	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 refers to the claim limitation the first guide and advancement structure providing a helical pathway (see lines 37-44). It is unclear what “the first guide and advancement structure providing a helical pathway” the claim is referring to in the claims. The claims are unclear because Applicant appears to be referring to two different structural features, the first guide and advancement structure of one tool and the first guide and advancement structure of another tool, by using the same term in the claims, thereby making the claims confusing to the reader.

Claim Objections

Claims 1, 3 and 5 objected to because of the following informalities: Similar to the above rejection of claim 4 under 35 U.S.C. 112, second paragraph, it is noted that claims 1, 3 and 5 also use the same wording to describe different structural limitations, i.e. “first helically guide and advancement structure,” making the claims somewhat difficult to understand.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1- 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Choi (US 2001/0023350).

Choi discloses a tool set (FIGS. 9, 13) for implanting a spinal rod in a patient; the tool set comprising a pair of end guide tools (FIG. 9, ref. #30); each of the end guide tool being non integral with and adapted to be selectively joinably attached at a lower end thereof to a respective spinal implant bone screw; each of the end guide tools including a longitudinal guide channel (FIG. 7(a), ref. #36) extending upwardly from the lower end thereof; each of the channels being sized and shaped to be adapted to receive opposite ends of the rod for operably guiding the rod ends toward respective bone screws; each of the end guide tools have a helically wound first guide and advancement structure (FIG. 7(a), ref. #35) located near a bottom thereof; the first guide and advancement structure providing a helical pathway adapted to rotatably and matingly receive a mating structure of a bone screw closure top (ref. #20); and the first guide and advancement structure also being adapted to be aligned during joining with a respective bone screw with a second guide and advancement structure (ref. #11) on such a respective bone screw so as to continue the helical pathway when a respective guide tool is joined with such a respective bone screw and so as to be adapted to

transfer the closure top between a respective guide tool and a respective bone screw upon rotation of the closure top. An intermediate guide tool (ref. #30) for use with a separate spinal implant bone screw; the tool including lower attachment structure (ref. #38) adapted for removable attachment to a respective bone screw; a longitudinal pass through slot (ref. #36) extending from a bottom thereof upward and being adapted to receive therethrough and guide the rod to a bone screw attached to the intermediate guide tool; a helically wound first guide and advancement structure (ref. #35) located near a bottom of the intermediate guide tool; the first guide and advancement structure providing a helical pathway adapted to rotatably and matingly receive a mating structure of a bone screw closure top (ref. #20); and the first guide and advancement structure also being adapted to be aligned with a second guide and advancement structure (ref. #11) on a bone screw so as to continue the helical pathway when the guide tool is attached to a bone screw and so as to be adapted to transfer the closure top between the guide tool and the non integral bone screw upon rotation of the closure top. A vertebral support rod implantation kit adapted for use with a plurality of vertebra (see FIG. 8) including a plurality of polyaxial bone screws (see FIG. 9) with each bone screw being adapted for implantation in one vertebra; each of the bone screws having a mating attachment structure (ref. #19); an elongate rod (ref. #40) sized and shaped to extend between a pair of end bone screws of the plurality of bone screws; a pair of end guide tools (ref. #30) separate from the bone screws; each of the end guide tools being non integral relative to a bone screw and including an end guide tool attachment structure (ref. #38) at a lower end thereof that operably and removably connects with

the bone screw mating attachment structure of a respective bone screw; each of the end guide tools including a longitudinal guide channel (ref. #36) extending upwardly from near the lower end thereof; each of the channels being sized and shaped to slidably receive opposite ends of the rod for operably guiding the rod ends toward respective bone screws; each of the end guide tools have a first helically wound guide and advancement structure (ref. #35) located near a bottom thereof the first guide and advancement structure providing a helical pathway adapted to rotatably and matingly receive a mating guide and advancement structure of a bone screw closure top; and the first guide and advancement structure also being operably alignable with a second guide and advancement structure (ref. #11) located on a respective bone screw so as to continue the helical pathway when a respective guide tool is selectively joined to a respective bone screw and so as to be adapted to transfer the closure top between a respective guide tool and the bone screw upon rotation of the closure top. The closure top has the mating guide and advancement structure thereon (ref. #24).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 rejected under 35 U.S.C. 103(a) as being unpatentable over Choi (US 2001/0023350) using a different interpretation.

In FIG. 14, Choi discloses an integral guide tool (ref. #51, FIG. 10) and bone screw (ref. #17). Each of the end guide tools including a longitudinal guide channel (channel separating upwardly extending arms of ref. #51) extending upwardly from the lower end thereof; each of the channels being sized and shaped to be adapted to receive opposite ends of the rod (ref. #40) for operably guiding the rod ends toward respective bone screws; each of the end guide tools have a helically wound first guide and advancement structure (ref. #11, above cutting line ref. #55) located near a bottom thereof; the first guide and advancement structure providing a helical pathway adapted to rotatably and matingly receive a mating structure of a bone screw closure top (ref. #20); and the first guide and advancement structure also being adapted to be aligned during joining with a respective bone screw with a second guide and advancement structure (ref. #11, below cutting line ref. #55) on such a respective bone screw so as to continue the helical pathway when a respective guide tool is joined with such a respective bone screw and so as to be adapted to transfer the closure top between a respective guide tool and a respective bone screw upon rotation of the closure top. The closure top mating guide and advancement structure and the bone screw second guide and advancement structure include interlocking members so as to be interlocking upon being mated.

Choi discloses the claimed invention except for the guide tool being non integral with the bone screw and being selectively operably connectable to the bone screw, and the first guide and advancement structure being a square thread.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the guide tool of Choi being non integral and selectively operably connectable to the bone screw, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179. Furthermore, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the first guide and advancement structure, or screw threads, of Choi, being square threads, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a first guide and advancements structure (threads). *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Response to Arguments

Applicant's arguments filed 12/26/2007 have been fully considered but they are not persuasive.

With regard to the statements of intended use and other functional statements, i.e. "removable," or capable of being removed, they do not impose any structural limitations on the claims distinguishable over Choi (US 2001/0023350) which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the

reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Also, a "cap" can be considered to be a "tool" that is capable of guiding a rod.

The rejections are deemed proper.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/
Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733